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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/987,899      | 11/16/2001  | Nordine Cheikh       | 16517.258           | 7754             |

7590 01/26/2005

Monsanto Company  
Patent Department  
Mail Zone E2NA  
800 N. Lindbergh Boulevard  
St. Louis, MO 63167

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| EXAMINER |
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MARSCHEL, ARDIN H

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1631

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/987,899

Applicant(s)

CHEIKH ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/2/04, 7/2/04, & 10/25/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 23-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: SEQ. ID NO: 5 match

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### **DETAILED ACTION**

Applicants' arguments, filed 3/2/04, 7/2/04, and 10/25/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **NEW MATTER**

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 27 cites a sequence identity between 100% and 98% in line 2. The 98% sequence identity evaluation parameter has not been found as filed. Applicants also did not point to written support for this parameter value. This limitation therefore is NEW MATTER.

### **LACK OF UTILITY REJECTION**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 23-28 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

This rejection is maintained and reiterated from the previous office action, mailed 12/2/03, and additionally applied to newly added claims 23-28 for the reasons of record. Applicants argue in REMARKS, filed 10/25/04, the claimed nucleic acid molecules are useful for isolating a variety of agronomically significant genes, acquiring molecular markers, etc. In response these are general speculations as to usefulness without any specific or substantial connection to any of them for the instantly claimed invention. For example, applicants have failed to specify even a single agronomically significant gene that has some type of currently available utility. This, and the other usefulnesses, equally suffer from any specific or substantial currently available utility. These arguments therefore are allegations without factual support and therefore non-persuasive. Applicants then argue that these uses are analogous to a microscope. In response this analogy is not persuasive because a microscope is well known to be useful in specifically and substantially identifying diseased cells or pathogens, none of which is currently available via the instant invention. Applicants then argue by setting forth a legal decision that an invention need not be the best or only way to accomplish a certain result. In response this rejection has not been based on any "best" or "only way to accomplish a certain result" requirement and therefore this argument is not directed to the basis for this rejection and is non-persuasive. Applicants then argue that this rejection implies that a new golf club does not have utility. In response no golf club analogy has been set forth a basis for this rejection, especially since a golf club has a well known exercise and recreational utility, neither of which have been alleged or are present regarding the instantly claimed invention. Applicants argue further that the

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instant invention is useful to identify a unique subset of related sequences. In response, such identification fails to indicate any specific or substantial use for such identification in currently available form and is again non-persuasive. Applicants then argue that the instant invention was isolated from maize and "may function" in plant growth etc. This "may function" admission by applicants supports this rejection in that such speculation fails to define what function or that the function, in fact, is substantial. Applicants then argue that SEQ ID NO: 5 is similar to the sequences of ribulose-bisphosphate carboxylase enzymes. In response several references have been previously provided with clearly bring into question the usability of sequence similarity to support a function such as sequence similarity to establish the enzyme activity encoding character of the instant invention. Applicants have not argued nor negated these references as support for this aspect of this rejection and therefore have not overcome this rejection basis, but rather only allege that these references are not applicable to the instant sequence similarity function assignment. This is an argument without any reasoning or basis as to why the documented controversy as to using sequence similarity to assign function is not applicable to the instant invention and therefore is non-persuasive. Applicants then argue that using sequences in microarray technology is well known. In response, it is acknowledged that microarray technology is well known, but that each sequence utilized therein provides information and has utility only if there is already some type of specific and substantial utility associated with such a sequence. The instantly claimed invention lacks such specific and substantial utility and therefore does not have utility in microarray technology either. Applicants then argue that no evidence has been

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provided to doubt the asserted utilities of the instant invention. In response this is factually incorrect because references have been provided and thus this argument is non-persuasive. Applicants then argue that credibility has not been assessed. In response credibility is one of three criteria that together must be satisfied in order to support utility for the claimed invention. Thus, the lack of any one of a specific or substantial utility supports this rejection even without credibility assessment. The instant invention lacks both specific and substantial utility. Also, credibility is generally assessed on the basis of whether an invention may be credible rather than incredible such as a perpetual motion machine, for example. It is deemed credible that a nucleic acid may be some type of utility, but that utility requires the combination of a specific, substantial, and credible utility, or, alternatively, a well known utility. No well known utility has been alleged or known for the instant invention.

Claims 1 and 23-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 and 23-28 lack enablement due to a lack of specific and substantial utility as discussed above and therefore the instant invention has not been set forth so as to support a use thereof.

### PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 23-28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Matsuoka et al. [J. Biochem. 102:673 (1987)].

The attached sequence comparison between the instant SEQ ID NO: 5 and Figure 1 sequence shown on page 674 of Matsuoka et al. reveals that the query match percent identity is 96.3 % with the local similarity which is reasonably a sequence identity value of 99.7 %. Matsuoka et al. discloses the cDNA via its sequence as encoding ribulose - 1,5 - biphosphate carboxylase as also cited in the instant claims regarding SEQ ID NO: 5. The cDNA of the reference has been cloned and substantially purified in order to sequence it as stated in the reference on page 674, first and second columns. Double stranded cDNA was also formed which is directed to a complement of the sequence in Figure 1 of the reference as well as a complement of the instantly claimed nucleic acid characterized via SEQ ID NO: 5. It is noted that the less than 100% sequence identity match between the cDNA of the reference and SEQ ID NO: 5 still results in the complement as instantly claimed anticipating those embodiments of the instant claims due to the complement being defined in the instant specification on page 71 to be inclusive of a molecule which can hybridize to another nucleic acid under high-stringency conditions. The sequence matching identities of 96.3 and 99.7 % both

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fall well within characteristics which hybridize under high-stringency. Also, the fragment limitation in instant claim 1 is anticipated due to the clearly shown fragment sequence identity on the sequence match listing as attached. Thus, all of the instantly pending claims are anticipated.

Claims 1 and 23-28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the 1990 Sigma Chemical Catalog disclosure of either of products O 4128, O8628, or O 8878.

This rejection is maintained and reiterated from the previous office action, mailed 12/2/03, and applied to newly added claims due to broadly defined complements therein. Applicants argue that the nucleic acid embodiments of the instant claims must encode the enzyme as stated in instant claim 1. In response, the "fragment thereof" limitation in instant claim 1 reasonably is interpreted as a fragment of any size from a nucleic acid encoding the maize or soybean enzyme cited in instant claim 1. Thus, the nucleic acid embodiments corresponding to a "fragment thereof" is not itself required to encode such an enzyme but rather may only be a fragment thereof as already explained as contained in the above products thus supporting maintaining this rejection. Similarly, the broad inclusive complement definition in the instant specification on pages 71-72 also are inclusive of small complementary nucleic acids which also are anticipated via the products of said reference.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices



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published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., AU 1631 Supervisory Patent Examiner, whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 24, 2005

*Ardin H. Marschel* 1/24/05  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER

SEQ ID NO: 5 match

MZEPCCSU  
LOCUS MZEPCCSU 830 bp mRNA linear PLN 13-NOV-1997  
DEFINITION Zea mays mRNA for ribulose 1,5-bisphosphate carboxylase small subunit, complete cds.  
ACCESSION D00170  
VERSION D00170.1 GI:217963  
KEYWORDS RuBPC; ribulose-1,5-bisphosphate carboxylase; small subunit.  
SOURCE Zea mays  
ORGANISM Zea mays  
Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta; Spermatophyta; Magnoliophyta; Liliopsida; Poales; Poaceae; PACCAD clade; Panicoideae; Andropogoneae; Zea.  
REFERENCE 1 (bases 1 to 830)  
AUTHORS Matsuoka, M., Kano-Murakami, Y., Tanaka, Y., Ozeki, Y. and Yamamoto, N.  
TITLE Nucleotide sequence of cDNA encoding the small subunit of ribulose-1,5-bisphosphate carboxylase from maize  
JOURNAL J. Biochem. 102 (4), 673-676 (1987)  
MEDLINE 88139216  
PUBMED 3436948  
COMMENT Comparison with the RuBPC small subunit genes from other plants revealed that the maize small subunit is similar to the wheat one, there being 73% homology between the transit peptides and 64% between the mature proteins. This indicates that there is no noteworthy difference between the C3 and C4 small subunit structures.  
FEATURES  
source Location/Qualifiers  
1..830  
/organism="Zea mays"  
/mol\_type="mRNA"  
/db\_xref="taxon:4577"  
/tissue\_type="leaf"  
66..578  
CDS  
/note="SSu"  
/codon\_start=1  
/product="ribulose 1,5-bisphosphate carboxylase small subunit"  
/protein\_id="BAA00120.1"  
/db\_xref="GI:217964"  
/translation="MAPTVMMASATAVAPFQGLKSTASLPVARRSSRLGNVSNNGGR  
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TSPCYDGRYWTMWKLPMPFGCNDATQVYKELQEAIKSYPDAFHRVIGFDNIKQTQCVS  
FIAYKPPGSD"  
BASE COUNT 147 a 281 c 220 g 182 t  
ORIGIN  
Query Match 96.3%; Score 311; DB 8; Length 830;  
Best Local Similarity 99.7%; Pred. No. 2.3e-48;  
Matches 322; Conservative 0; Mismatches 0; Indels 1; Gaps 1;  
QY 1 CGACCTGCTGAAGCAGGTGGACTACCTGCTGCGCAACGGCTGGATACCTGCCTCGAGTT 60  
|||||  
Db 278 CGACCTGCTGAAGCAGGTGGACTACCTGCTGCGCAACGGCTGGATACCTGCCTCGAGTT 337  
QY 61 CAGCAAGGTCTGGCTTCGTGTACCGCGAGAACTCCACCTCCCCGTGCTACTACGACGGCCG 120  
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Db 338 CAGCAAGGTCTGGCTTCGTGTACCGCGAGAACTCCACCTCCCCGTGCTACTACGACGGCCG 397  
QY 121 CTACTGGACCATGTGGAAGCATGCCCATGTTTCGGCTGCAACGACGCCACCCAGGTGTACA 180  
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QY 181 AGGAGCTGCAGGAGGCCATCAAATCCTACCGGACGCCTTCCACCGCGTCATCGGCTTCG 240  
|||||  
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QY 241 ACAACATCAAGCAGACGCGAGTTCGCTCAGCTTCATCGCCTACAAGCCCCGGGCGAGCGACT 300  
|||||  
Db 517 ACAACATCAAGCAGACGCGAGTTCGCTCAGCTTCATCGCCTACAAGCCCCGGGCGAGCGACT 576  
QY 301 AGACCGCGCCCGCCGCCGCC 323  
|||||  
Db 577 AGACCGCGCCCGCCGCCGCC 599